

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

October 31, 1977

Honorable Stansfield Turner
Director
Central Intelligence Agency
Washington, D.C. 20505

Dear Admiral Turner:

A draft summary of the proposed directive governing the protection of human subjects in research conducted or supported by the Intelligence Community is enclosed. This summary is based on information that was supplied by memorandum dated 17 May 1977 from Walter Elder. In view of the passage of time since that memorandum, our summary is being provided herewith in draft form so that it may be reviewed for accuracy prior to its inclusion in a report to be issued by this Commission.

The information was originally requested pursuant to Public Law 93-348, which authorizes and directs the National Commission for the Protection of Human Subjects to secure directly from departments or agencies of the United States information necessary to enable the Commission to conduct a study and make recommendations to Congress regarding the need for a mechanism to protect human subjects of biomedical and behavioral research that is not regulated by the Secretary of Health, Education, and Welfare, e.g., research conducted or supported by other departments and agencies.

Your cooperation in providing any necessary additions, corrections or comments on the enclosed summary will be greatly appreciated. In addition, we would appreciate receiving copies of applicable regulations, directives, manuals, statements of policy, etc. that are not indicated to have been transmitted previously.

Sincerely yours,

Michael S. Yesley
Michael S. Yesley
Staff Director

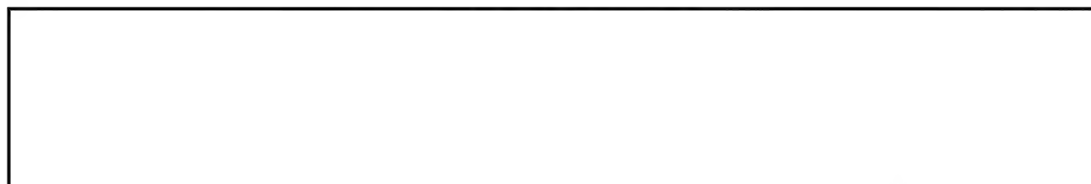
Enclosure

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Authority: Executive Order 11905 (February 18, 1976); Draft Director of Central Intelligence Directive IC-77-4563 (17 May 1977); statement of Admiral Stansfield Turner, Director of Central Intelligence, before the Senate Select Committee on Intelligence (3 August 1977).

Applicability: The Executive Order applies to experimentation with drugs on human subjects conducted or supported by Intelligence Community agencies; the draft Directive applies to all research conducted or supported by Intelligence Community Agencies.

Review Procedures: In the draft directive, the Intelligence Community adopts the provisions of DHEW regulations (45 CFR 46), with the following addition. No more than half the members of an IRB may represent Intelligence Community organizations, even when all IRB members must have security clearance in order to review classified research.

Each component of the Intelligence Community must establish procedures to implement the directive. One requirement is the appointment of an "agency expert" who will be responsible for determining that Institutional Review Boards are established in compliance with the regulations, and who will also serve as the point of contact for subjects participating in intramural research. The resident expert must remain knowledgeable on matters

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pertaining to the protection of human subjects, and maintain contacts with the National Commission for the Protection of Human Subjects, the Department of Health Education and Welfare, and other appropriate federal agencies, soliciting guidance and consultation, as necessary on specific proposals or general issues.

Review Standards: In the draft directive, the Intelligence Community adopts the review standards of DHEW regulations (45 CFR 46).

Consent Provisions: In the draft directive, the Intelligence Community adopts the provisions of DHEW regulations (45 CFR 46) with the following additions. Consent documents must be signed in the presence of a disinterested third party. In addition, when the research is of a classified nature, subjects may be required to sign an agreement not to disclose information regarding the research to other members of the public, or they may be informed that the sponsor of the research prefers to remain anonymous. The subject must indicate willingness to participate under such conditions on the consent document. In no event, however, may security considerations "constitute a basis for contravening the informed consent requirements."

Special Subjects: When members of the military, U.S. government employees or employees of U.S. government contractors are enrolled as research subjects "scrupulous attention shall be paid to ensure that no coercion is directed to the employee as a means of securing his or her participation. Data collected as a result of the employee participating in the research shall not be incorporated in subject's personal file." [Quotation from draft directive.]

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Additional Provisions: In the draft directive, the Intelligence Community requires adherence not only to present DHEW regulations but also to any future DHEW regulations adopted pursuant to the recommendations of the National Commission for the Protection of Human Subjects.

Sanctions: Contract funds may be withdrawn in the case of noncompliance. No sanctions are provided in the case of noncompliance in research conducted within the Intelligence Community.

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Routing Slip

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SUSPENSE		<div style="border: 1px solid black; border-radius: 50%; padding: 5px; display: inline-block;"> <u>17 Nov 77</u> Date </div>			

Remarks: Per our telecon, please prepare DCI response

Shanne Rankin
Executive Secretary
11/3/77